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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,188	05/09/2001	Ilham Mohamed Saleh Saeed Abuljadayel	674528-2003.1	6161
20999 7590 02/19/2010 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER CANELLA, KAREN A	
			ART UNIT 1643	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/853,188

**Applicant(s)**ABULJADAYEL, ILHAM  
MOHAMED SALEH SAEED**Examiner**

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, 34-41, 101, 104, 105 and 107 is/are rejected.
- 7) ☒ Claim(s) 106 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,5,7,11,13,15,17,19,20,22,23,25,26,28-32,34-41,101 and 104-107.

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2010 has been entered.

Claims 1, 2, 40 and 41 have been amended. Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, 34-41, 101 and 104-107 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32 and 34-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 40 and 41 recite the limitation wherein the chamber, the input storage container and the output storage container are "disposable". The word "disposable" is a subjective term subject to interpretation between routineers. The metes and bounds of that which encompasses a disposable chamber, and input and output storage containers are unclear. Plastic tissue culture bottles and flasks as well as plastic blood bags are clearly manufactured to be disposable, however it is unclear if other container substances, such as glass chamber, bottles, tubes and bags fall within the scope of what applicant intends to claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 15, 19, 20, 22, 23, 25, 26, 28-32, 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Koketsu et al (US 5,834,423).

Claim 1 is drawn to a device comprising:

- (a) a chamber;
  - (b) means for introducing a cell population including committed cells from an input storage container;
  - (c) means for introducing an agent into said chamber;
  - (d) incubation means for incubating said committed cells in the presence of said agent;
  - (e) mixing means for mixing the agent and the cell population; and,
  - (f) means for removing a sample of cells from the chamber into an output storage bag;
- wherein the chamber, input storage container and output storage container are disposable.

Claim 2 is drawn to a device comprising:

- (a) a chamber;
  - (b) means for introducing a cell population including committed cells from an input storage container;
  - (c) means for introducing an agent into said chamber;
  - (d) incubation means for incubating said committed cells and said agent;
  - (e) mixing means for mixing the agent and the cell population in the chamber; and,
  - (f) means for removing a sample of cells from the chamber into an output storage bag;
- wherein the chamber, input storage container and output storage container are disposable.

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Claim 3 embodies the device of claim 1 wherein said device comprises a transfer means, a harvesting means and a removal means, wherein the means for introducing an agent into the chamber is a transfer means for transferring a volume of the agent to the chamber and/or a transfer means for transferring a calculated volume of agent to the chamber.

Claim 40 is drawn to a device comprising:

- (a) a chamber;
  - (b) means for introducing a cell population including committed cells from an input storage container;
  - (c) means for introducing an agent into said chamber;
  - (d) incubation means for incubating said committed cells in the presence of said agent;
  - (e) mixing means for mixing the agent and the cell population in the chamber; and,
  - (f) means for removing a sample of cells from the chamber into an output storage bag;
- wherein the chamber, input storage container and output storage container are disposable.

Claim 41 is drawn to a device comprising:

- (a) a chamber;
  - (b) means for introducing a cell population including committed cells from an input storage container;
  - (c) means for introducing an agent into said chamber;
  - (d) incubation means operable to incubating said committed cells and said agent;
  - (e) mixing means for mixing the agent and the cell population in the chamber; and,
  - (f) means for removing a sample of cells from the chamber into an output storage bag;
- wherein the chamber, input storage container and output storage container are disposable.

Claims 1, 2, 40 and 41 recite "for forming and/or increasing the relative number of undifferentiated cells in a cell population comprising hematopoietic cells, including committed

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cells", "and "for forming and/or increasing the relative number of cells having a cell surface marker designation CD34+ and/or HLA-DR- and/or CD38- and/or CD117 and/or AC133 and/or CD90 and/or CD45<sup>low</sup> in a cell population comprising hematopoietic cells, including committed cells". Said recitations have not been given patentable weight because they occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is further noted that the limitations of claims 15, 19, 20, 22, 23, 25, 26, 28-32 and 34-41 are drawn to the intended use of the claimed device, said intended use not having patentable weight. The instant claims do not require that the recited cell populations and agents are present within the device, only that the means exists for placing the cell populations and agents within the device, and means exist for the removal of the cell population from said device.

Koketsu et al disclose a roller bottle shaking at 37 degrees (column 22, lines 53-55). When given the broadest reasonable interpretation, a roller bottle is disposable, and thus fulfills the specific embodiment of a chamber. The cap of the roller bottle fulfills the specific requirement of (b) means for introducing a cell population including committed cells from an input storage container; (c) means for introducing an agent into said chamber; and (f) means for removing a sample of cells from the chamber into an output storage bag in claims 1, 2, 40 and 41, as well as the transfer means, harvesting means and removal means of claim 3, because the unscrewing of the roller bottle cap provides the "means" for material transfer. The shaking water bath at 37 degrees meets the limitation of mixing means and incubation means.

Claims 1-3, 15, 19, 20, 22, 23, 25, 26, 28-32, 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Barenholz et al (U.S. 4,812,314).

Barenholz et al disclose a 25ml culture flask incubated on a gyratory shaker at 37 degrees C (column 14, lines 51-52). The cap of the culture flask fulfills the specific requirement of (b) means for introducing a cell population including committed cells from an input storage

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container; (c) means for introducing an agent into said chamber; and (f) means for removing a sample of cells from the chamber into an output storage bag in claims 1, 2, 40 and 41, as well as the transfer means, harvesting means and removal means of claim 3, because the unscrewing of the cap provides the "means" for material transfer. The gyratory shaker at 37 degrees meets the limitation of mixing means and incubation means.

Claims 1-3, 15, 19, 20, 22, 23, 25, 26, 28-32, 34-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al (U.S. 6,054,587).

Reddy et al disclose a 50-ml Falcon tube incubated in a shaking water bath at 37 degrees C (column 70, lines 55-56). The cap of the tube fulfills the specific requirement of (b) means for introducing a cell population including committed cells from an input storage container; (c) means for introducing an agent into said chamber; and (f) means for removing a sample of cells from the chamber into an output storage bag in claims 1, 2, 40 and 41, as well as the transfer means, harvesting means and removal means of claim 3, because the unscrewing of the cap provides the "means" for material transfer. The shaking water bath at 37 degrees meets the limitation of mixing means and incubation means.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 101, 104, 105 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palsson et al (U.S. 5,888,807).

Claim 101 is drawn to a device comprising:

- (a) a support hook;
- (b) a heated incubation chamber;



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(c) means for drawing the starting cell population from the inlet storage container into the heated incubation chamber;

(d) a refrigerated chamber for insertion of a syringe;

(e) means for delivering an agent from the refrigerated chamber into the heated chamber;

(f) means for mixing an agent and a cell population in the heated incubation chamber;

(g) means for hanging an outlet storage container;

(h) means for drawing the treated cell population from the heated incubation chamber into the outlet storage container.

Claim 104 embodies the device of claim 101 wherein the means for drawing the starting cell population from the inlet storage container is a peristaltic pump. Claim 105 embodies the device of claim 101 wherein the means for drawing the treated cell population into the outlet storage container is a peristaltic pump. Claim 107 embodies the device of claim 101 wherein the means for delivering the agent from the refrigerated chamber into the heated chamber comprises a stepper motor for discharging a syringe.

Claim 104 recites a device “for treating a starting hematopoietic cell population comprising hematopoietic cells with an agent selected from the group consisting of (a) an antibody that binds to MHC antigens, (b) erythropoietin, and (c) GM-CSF, and capable of increasing the relative number of undifferentiated cells”. Said recitation has not been given patentable weight because they occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is further noted that the limitations of claim 101(a) and (g), support hook “for the attachment of an inlet storage container containing a starting cell population, wherein said inlet storage container is a blood bag” does not actually require that the storage container or a blood bag be on the support hook, nor does the means for hanging an outlet storage container, wherein the outlet storage container is a blood bag actually require that the outlet storage container or a blood bag be on the “means for hanging”.

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Palsson et al teach devices for maintaining and growing human stem and/or hematopoietic cells including a refrigerated chamber connecting to the incubation chamber by means of a syringe pump or peristaltic pump(column 23, lines 13-18). Palsson et al teach the mixing of fluids from a number or inlet port such that the cells will be exposed to a uniform liquid (column 15, lines 49-52). Palsson et al teach means for harvesting the non-adherent cells from the bioreactor (column 21, lines 36-48). Palsson et al do not teach a support hook, or means for hanging an outlet storage container.

It would have been prima facie obvious t the time that the claimed invention was made to have two support hooks. One of skill in the art would have been motivated to d so in order to hang a checklist of operating instructions and to hang a notebook for recording observations. It is noted that as claim 101 is written, the support hook and the means for hanging do not contribute to the functioning of the claimed device.

Claim 106 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in a prior Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643